DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 24 2006

Re: Prialt
Docket Nos.: 2005E-0246 and 2005E-0239

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,795,864, and 5,364,842 filed by Elan Pharmaceuticals, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Prialt, the human drug product claimed by the patents.

The total length of the regulatory review period for Prialt is 3,801 days. Of this time, 1,973 days occurred during the testing phase and 1,828 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 4, 1994.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 4, 1994.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 28, 1999.

   FDA has verified the applicant's claim that the new drug application (NDA) for Prialt (NDA 21-060) was initially submitted on December 28, 1999.

3. The date the application was approved: December 28, 2004.

   FDA has verified the applicant's claim that NDA 21-060 was approved on December 28, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner
901 New York Ave., NW
Washington, DC 20001-4400